



U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

March 16, 2015

BY ECF

Honorable James C. Francis
United States Magistrate Judge
U.S. Courthouse, 500 Pearl Street
New York, NY 10007

Re: *United States ex rel. Kester v. Novartis Pharmaceuticals, Corp.*, 11 Civ. 8196 (CM) (JCF)

Dear Judge Francis:

On behalf of the United States (the “Government”), and in accordance with the Court’s directions at the March 4th discovery teleconference, we respectfully submit this letter to seek an order compelling Novartis to produce documents concerning legal advice relating to its relationship with the specialty pharmacies dispensing Myfortic. As set forth below, Novartis intends to assert a “good faith defense” as to the Government’s Myfortic claims. Under Second Circuit law, the assertion of this defense “implicitly waives” the attorney-client privilege. *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991). Further, on Friday, the Novartis executive who oversaw Novartis’s relationships with the Myfortic pharmacies from 2010 to 2012 testified he relied on the expertise of Novartis’s lawyers in concluding that his team’s interactions with pharmacies complied with the AKS. In light of these circumstances, Novartis is not entitled to simultaneously assert its alleged good faith while shielding from discovery basic facts concerning whether and how it sought legal advice, what legal advice it obtained, and whether it duly followed such advice.

I. BACKGROUND

The Government alleges that Novartis violated the FCA and the AKS in its relationships with specialty pharmacies dispensing two drugs – Myfortic and Exjade. The crux of the Myfortic allegations is that Novartis offered specialty pharmacies the ability to earn performance rebates on their Myfortic sales to induce those pharmacies to recommend Myfortic and/or recommend against competitor drugs.

Novartis has stated it intends to assert a “good faith defense” as to the Myfortic claims — specifically, that “it acted in good faith in connection with its interactions with” the Myfortic pharmacies.¹ See 2/20/15 R. Skaistis e-mail to L. Yu. Further, on Friday, James Niebanck, a Novartis executive who oversaw Novartis’s relationships with the Myfortic pharmacies from 2010 to 2012, testified that (i) it was his responsibility to ensure that both he and the account managers under his supervision complied with the AKS in their interactions with specialty pharmacies, (ii) he understood that, for contracting with specialty pharmacies, “there is [sic] attorneys on behalf of Novartis reviewing everything that we did,” and (iii) he “relied on” the

¹ Novartis submitted this e-mail, which appears in a series of e-mails exchanged between the Government and Novartis counsel, as an attachment to its March 2nd letter to the Court. For the Court’s convenience, we have attached a copy of that e-mail chain as Exhibit A to this letter.

legal “expertise ... [of] lawyers, whether they’re in-house or outside, who review[ed] the contracts.” See Niebanck Dep. Tr. at 84–99.² Mr. Niebanck’s predecessor, Robert Rindini, also was asked at his CID deposition about his “understanding as to what specific types of scenarios [in contracting with specialty pharmacies] would be deemed inappropriate *quid pro quos*,” and Mr. Rindini testified that he “didn’t think there were any because they were reviewed by our legal internal and ... if there was that issue, that would be picked up before a contract ever went to a customer.” See Rindini CI Dep. Tr. at 92.³

Despite having decided to assert a “good faith defense,” and despite its own executives’ testimony regarding reliance on legal review, Novartis nonetheless is continuing to invoke the attorney-client privilege to prevent the Government from inquiring into (i) what facts the Novartis employees working on Myfortic provided to counsel, (ii) what advice the attorneys gave concerning relationships with the Myfortic pharmacies, and (iii) whether the Novartis employees working on Myfortic in fact followed counsel’s advice concerning those relationships. As set forth below, Novartis’s position is not supported by Second Circuit law and, in any event, is inconsistent with its prior representation concerning the scope of its waiver.

II. NOVARTIS’S GOOD FAITH DEFENSE WAIVES PRIVILEGE

By asserting a “good faith” defense, Novartis has “implicitly waived” privilege over attorney-client communications relating to the Myfortic scheme. *Bilzerian*, 926 F.2d at 1292. In *Bilzerian*, the criminal defendant sought to testify “that he thought his actions were legal.” *Id.* But *Bilzerian*, like Novartis, did not want to reveal his communications with his lawyers. The district court held that a defendant cannot have it both ways — if *Bilzerian* raised this defense, he would also have to disclose the legal advice he received. The Second Circuit affirmed, holding that, by raising a good faith defense, a defendant “put[s] his knowledge of the law and the basis for his understanding of what the law required in issue. His conversations with counsel regarding the legality of his schemes would have been directly relevant in determining the extent of his knowledge and, as a result, his intent.” *Id.*

The Eleventh Circuit has addressed the same question as *Bilzerian*, this time in a case in which a corporation wished to assert its good faith but without relying on specific legal advice — and reached the same answer. See *Cox v. Adm’r U.S. Steel & Carnegie*, 17 F.3d 1386, 1418 (11th Cir.), *opinion modified on reh’g*, 30 F.3d 1347 (11th Cir. 1994) (in civil RICO suit, corporation implicitly waived attorney-client privilege by asserting that it “believed [its] policy to be lawful”). There, the defendant — like Novartis, and *Bilzerian* before it — did not seek to rely on advice of counsel: “USX has denied any intent to assert a defense of advice of counsel or to rely on any privileged attorney-client communications in its defense.” *Id.* Nevertheless, the Eleventh Circuit affirmed the district court’s conclusion that “USX’s defense ... necessarily implicates all of the information at its disposal when it made the decision to change the leave of absence policy and later, to rescind the change.” *Id.* Reasoning that “it would be inequitable to allow USX to present evidence tending to show that it intended to comply with the law, while allowing it to cloak in privilege those documents tending to show it might have known its actions did not conform to the law,” the Eleventh Circuit affirmed that USX waived the attorney-client

² Relevant excerpts from Mr. Niebanck’s deposition transcript are attached as Exhibit B. Novartis has designated this transcript and Exhibits C, D, E, and F below as “Confidential” pursuant to the Protective Order. Accordingly, we are submitting these exhibits under seal.

³ Relevant excerpts from this CID deposition transcript are attached as Exhibit C.

privilege with regard to such communications.” *Id.*

District courts in the Second Circuit and elsewhere have agreed. In *Arista Records LLC v. Lime Group LLC*, Judge Wood noted that “a party may not assert that it believed its conduct was lawful, and simultaneously claim privilege to block inquiry into the basis for the party’s state of mind or belief.” 2011 WL 1642434, at *2-3 (S.D.N.Y. Apr. 20, 2011). Thus, because the defendants there had “repeatedly blocked Plaintiffs from conducting any discovery into their communications with counsel,” they were precluded from “assert[ing] their alleged good faith belief in the lawfulness of their conduct” at trial. *Id.*; see also *Barker ex rel. U.S. v. Columbus Reg’l Healthcare Sys., Inc.*, No. 4:12-CV-108 CDL, 2014 WL 4287744, at *4 (M.D. Ga. Aug. 29, 2014) (in *qui tam* suit, defendant corporation waived A/C privilege by asserting its belief that its purchase of health-care business was lawful); *United States v. Exxon Corp.*, 94 F.R.D. 246, 248 (D.D.C. 1981) (in suit by government to recover overcharges, Exxon, by “interposing the affirmative defense of good faith reliance on the government’s regulations and communications,” waived A/C privilege as to any “internal documents concerning interpretations of pertinent regulations”). Indeed, as the court noted in *Exxon*, “[m]ost courts considering the matter have concluded that a party waives the protection of the attorney-client privilege when he voluntarily injects into the suit the question of his state of mind.” 94 F.R.D. at 248.

Novartis posits that because it does not plan to specifically rely on “legal advice” in support of its “good faith” defense, it can hide any such advice from the Government. That position conflicts with *Bilzerian*, *Cox*, *Arista*, *Barker*, *Exxon* and other cases where the defendants also did not plan to rely on any legal advice at trial, but were nevertheless held to have waived privilege.⁴ Moreover, Novartis’s argument is patently unfair. If accepted, it would allow a defendant – having been advised by counsel that its planned actions may be unlawful – to claim it was wholly unaware of the illegality of such conduct, while at the same time hiding the evidence showing the claim to be false. The Court should reject Novartis’s unsupported and unjust argument.

III. NOVARTIS’S ASSERTION OF PRIVILEGE CONFLICTS WITH ITS PRIOR PRIVILEGE WAIVER

Novartis has acknowledged, as it must, that its privilege waiver “includes any legal advice during the relevant time period that bears on the challenged Exjade activities ([including] ... discounts, rebates ...) regardless of whether those materials specifically reference Exjade or adherence.” See Dkt. 357-1 at 4 (emphasis added). As noted above, Novartis chose to structure its relationships with the Myfortic pharmacies as “performance rebates.” Documents in Novartis’s “waiver” production show that, in connection with structuring its relationships with the Exjade pharmacies, Novartis also sought legal advice concerning “performance rebate” arrangements.

For example, in an August 13, 2008 email,⁵ Kenneth Olsen, a Novartis executive, asked for legal advice about “chang[ing] shipment rebate [for the Exjade pharmacies] to a purchases performance rebate.” Legal advice concerning performance rebate relationships between

⁴ Novartis’s position in this regard also is at odds with the sworn testimony of its own employees. As described above, James Niebanck and Robert Rindini – two executives who oversaw Novartis’s relationships with the Myfortic pharmacies – both testified under oath that they relied on legal review of such relationships. See *supra* at 2.

⁵ A copy of this e-mail is attached as Exhibit D to this letter.

Other documents further confirm that Novartis's Exjade team did not operate in a silo, closing its ears and eyes to legal advice provided to Novartis employees working on other drugs like Myfortic; instead, the Exjade team, in structuring its relationships with the Exjade pharmacies, not only had access to legal advice provided to teams working on other drugs, but *in fact* based its course of action on such advice. Thus, in a November 2007 e-mail,⁶ a Novartis executive, Paul Pochtar, advised the Exjade brand director, Peter Ng, that the Exjade team needed to “think through implications” of offering financial incentives to the Exjade pharmacies “based upon recent legal guidance relative to Tasigna/Gleevec Specialty Pharmacy agreements” A few days later, when Mr. Pochtar and his subordinates met with a member of the Exjade team to talk about offering financial incentives to the Exjade pharmacies, they again discussed how the “TGI [Tasigna Gleevec Initiative] Initiative has shown us that Monetary Incentive Goals present legal and structural challenges.” *See* NPCSP-5210071.

* * *

We thank the Court for its consideration of this letter.

PREET BHARARA
United States Attorney

By: /s/ Li Yu
LI YU
REBECCA C. MARTIN
DAVID J. KENNEDY
PETER M. ARONOFF
Assistant United States Attorneys
86 Chambers Street, 3rd Floor
New York, NY 10007
Tel.: (212) 637-2734/2714/2733/2697

⁶ Copies of this e-mail and the next e-mail discussed in this paragraph are attached to this letter as Exhibits E and F, respectively.

cc: (By E-mail and ECF)
Counsel for the Litigating States
Counsel for the Relator
Counsel for Novartis
Counsel for Accredo and CuraScript
Counsel for CVS